

K070238

FEB 28 2007

510(k) SUMMARY of Safety and Effectiveness

I. Applicant Information:

Date Prepared: January 19, 2007
Submitter: AGA Medical Corporation

Address: 5050 Nathan Lane North
Plymouth, MN 55442

Establishment
Registration No. 2135147

Contact Person: David D. Cox, Ph.D.
Senior Regulatory Affairs Manager

Telephone Number: (763) 531-3064
Fax Number: (763) 647-5932

II. Device Information:

Trade Name: AMPLATZER® Reliant™ Catheter Delivery System
Common Name: Catheter Delivery System

Classification Name: Catheter, Percutaneous
Classification: Class II, 21 CFR 870.1250
Product Code: DQY

Predicate Device: Medtronic® SelectSite® Deflectable Catheter Delivery System
510(k) No. K033989, Reg. No. 870.1250; Product Code: DQY

Predicate Device Intended Use: The deflectable catheter system is intended to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart, and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Device Description: The AMPLATZER® Reliant™ Catheter Delivery System is a sterile, single-use device designed to facilitate the introduction of transvenous devices within the chambers and coronary vasculature of the heart.

The catheter has a single lumen for passage of transvenous devices with maximum outer diameters of 6-12 French (2.0-4.0 mm). The catheters currently come in 60 cm and 80 cm usable lengths. The system includes the following components:

- Delivery Catheter – used to deliver transvenous devices
- Dilator – used within the Delivery Catheter to dilate the vessel and to help direct the Delivery Catheter during placement
- Loader– used to help introduce the selected implantable device into the delivery catheter
- Delivery Wire – attaches to the implantable device and facilitates advancement through the catheter, placement and, if desired, recapture of the specified implantable device. [If this surgical accessory (Product Code = DWS) is included, the labeling will specify compatibility with the appropriate implantable devices.]
- Vise – a handle that is attached to the Delivery Wire by means of a set screw
- Hemostasis Valve– used on the proximal end of the Loader to minimize bleeding from the Delivery Catheter and for flushing air from the system

Intended Use: The AMPLATZER® Reliant™ Catheter Delivery System is intended to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart.

Comparison to Predicate Device: The AMPLATZER® Reliant™ Catheter Delivery System is substantially equivalent to the predicate device cleared by K033989. The two systems are both handheld catheter systems designed to facilitate access and placement of specified implantable devices within the chambers and coronary vasculature of the heart. Both delivery catheters are single lumen design with a hemostasis valve and an included dilator and introducer.

Test Data: Verification and validation testing confirms that the functional characteristics of the AMPLATZER® Reliant™ Catheter Delivery System are substantially equivalent to the predicate device cited. This included catheter integrity, catheter kink resistance, leak resistance, hub strength and the ability to deliver various implantable devices.

Summary: Based on the technical information, intended use, laboratory verification tests and *in vitro* performance information provided, the AMPLATZER® Reliant™ Catheter Delivery System is substantially equivalent to the currently marketed predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AGA Medical Corporation
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

FEB 28 2007

Re: K070238
Amplatzer Reliant Catheter Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: February 6, 2006
Received: February 7, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

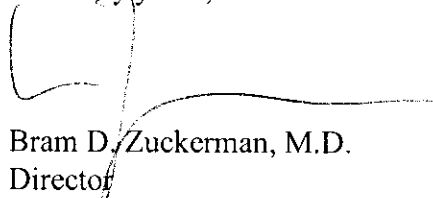
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a horizontal line.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K070238

Device Name: AMPLATZER® Reliant® Catheter Delivery System

Indications for use:

The AMPLATZER® Reliant™ Catheter Delivery System is intended to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart.

Prescription Use x
(Part 21 CFR 801 Subpart D)

OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DIVISION OF MEDICAL DEVICES

DIVISION OF

CDRH

AMPLATZER® Reliant® Catheter Delivery System

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